K131345

510(k) Summary

Nasseo, Inc.

TiArray Dental Implant System

AUG 07 2013

July 25, 2013

ADMINISTRATIVE INFORMATION

Manufacturer Name	Nasseo, Inc. 632 Missouri St., Unit 6 San Diego, CA 92109 Telephone: +1 (858) 736-4400
Official Contact	Garrett Cale Smith, Ph.D. CEO
Representative/Consultant	Allison C. Komiyama, Ph.D. Floyd G. Larson PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone: +1 (858) 792-1235 Fax: +1 (858) 792-1236 Email: akomiyama@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	TiArray Dental Implant System
Common Name	Dental implants and dental implant abuments
Classification Names	Endosseous dental implant Endosseous dental implant abutment
Classification Regulation	21 CFR 872.3640, Class II
Product Codes	DZE, NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

INTENDED USE

The TiArray Dental Implant System is intended to be surgically placed, either immediately or delayed, in the bone of the maxillary and/or mandibular arch to provide support for crowns, bridges or overdentures. When a one-stage surgical approach is applied, the implant may be immediately loaded when good primary stability is achieved and the functional load is appropriate.

DEVICE DESCRIPTION

TiArray Dental Implant System implants included in this submission are endosseous dental implants with an internal hex implant/abutment interface. They are designed to provide support for prosthetic teeth to restore chewing function. The implants are made of commercially pure titanium, with a surface that is etched and anodized. Implants are provided in a tapered, threaded design with micro-grooves around the neck of the implant and two cutting flutes. Straight abutments made of titanium alloy are provided for each diameter implant for cement-retained prostheses. The implant is available in three diameters (3.5, 4.3, and 5.0 mm), each in four lengths (8.0, 10.0, 11.5, and 13.0). The abutments come in three platform diameters (3.5, 4.3, and 5.0 mm) that correspond to the diameters of the implant.

EQUIVALENCE TO MARKETED DEVICE

The subject device is substantially equivalent to the following predicate devices:

- Nobel Biocare USA LLC., SFB & CFB Implants (K061003)
- Nobel Biocare USA LLC., NobelActive Internal Connection Implant (K071370)
- Implant Direct LLC., Spectra-System (K061319)

The implants of the subject TiArray Dental Implant System have a similar design (threaded body with micro-grooves at the collar) and dimensions (Ø3.5, 4.3, and 5 mm x 8, 10, 11.5, and 13 mm), use similar materials (CP titanium grade 4) and have a similar surface (titanium oxide) as those cleared under K061003 and K071370. The implants also have a similar design and dimensions and an identical internal connection (internal hex) as those cleared under K061319. The abutments of the subject TiArray Dental Implant System have a similar design and material (Ti-6Al4-V ELI titanium alloy) as those cleared under K061003, K071370 and K061319.

Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence include: biocompatibility, engineering analysis and dimensional analysis. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.

Clinical data were not submitted in this premarket notification.

CONCLUSIONS

The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject device and predicate devices encompass the same range of physical dimensions, including diameter and length of the implants, and diameter, height and angle of the abutments. The subject and predicate devices are packaged in similar materials and sterilized using similar methods. Any differences in the technological characteristics do not raise new issues of safety or efficacy. The device is safe and effective for its intended use and performs as well as or better than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 7, 2013

Nasseo, Incorporated
C/O Allison C. Komiyama, PhD
Senior Regulatory Specialist
PaxMed International, Limited Liability Company
12264 El Camino Real, Suite 400
San Diego, CA 92130

Re: K131345
Trade/Device Name: TiArray Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: May 9, 2013
Received: May 13, 2013

Dear Dr. Komiyama:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer -S

Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K131345

Device Name: TiArray Dental Implant System

Indications for Use:

The TiArray Dental Implant System is intended to be surgically placed, either immediately or delayed, in the bone of the maxillary and/or mandibular arch to provide support for crowns, bridges or overdentures. When a one-stage surgical approach is applied, the implant may be immediately loaded when good primary stability is achieved and the functional load is appropriate.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Andrew I. Steen -S
2013.08.06 14:39:26 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K131345